

A Clinical, Laboratory and Microbiological Evaluation on Efficacy of Dental Air Force Home Dental Cleaning System on Type 2 Diabetic and Nondiabetic Adult Chronic Periodontitis Patients: A 6-Month Clinical Study

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ABSTRACT

Aim: The study outlined to evaluate the clinical, laboratory and microbiological efficacy of Dental Air Force home dental cleaning system on type 2 diabetes and nondiabetic adult chronic periodontitis patients.

Materials and methods: A total of 100 adult chronic periodontitis subjects were recruited voluntary for this study. Clinical [plaque index (PI), gingival index (GI) and clinical attachment loss (CAL)], laboratory (C-reactive protein levels and glycated hemoglobin) and microbiological parameters were measured prior to phase 1 therapy; at 3rd and 6th month post phase 1 therapy. Comparative assessment was done among all the patients that were divided into four groups with Student paired t-test and analysis of variance (ANOVA).

Results: The results of this study showed that there was significant decrease in clinical, laboratory and microbiological parameters from baseline to 6 months in all the groups (i.e. $p < 0.01$). The subjects under groups using Dental Air Force home dental cleaning system showed highly significant reduction to all the parameters as compared to subjects under groups using toothbrush.

Conclusion: There was strong correlation between periodontal diseases and systemic parameters. Dental Air Force home dental cleaning system with the access to interdental area helps in preventing the accumulation of dental plaque biofilm, thus able to maintain the clinical, laboratory and microbiological parameters at much lower levels as compared to traditional tooth brushing after phase I therapy.

Keywords: Dental Air Force, CRP, Diabetes, HbA1c.

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INTRODUCTION

Periodontitis is a destructive inflammatory disease of the supporting tissues of the teeth and is caused either by specific microorganisms or by a group of specific microorganisms, resulting in progressive destruction of periodontal ligament and alveolar bone with periodontal pocket formation,

gingival recession, or both.¹ The predominant anaerobic microorganisms that play significant role are *Aggregatibacter actinomycetemcomitans*, *Porphyromonas gingivalis*, *Prevotella intermedia*, *Tannerella forsythia*, *Fusobacterium nucleatum*, *Peptostreptococcus micros*, and *Campylobacter rectus*.² Association of periodontal infection with organ systems like cardiovascular system, endocrine system, reproductive system, and respiratory system makes periodontal infection a complex multiphase disease. Inflamed periodontal tissues produce significant amounts of proinflammatory cytokines, mainly interleukin-1 beta (IL-1 β), interleukin-6 (IL-6), prostaglandin E2 (PGE2), and tumor necrosis factor alpha (TNF- α), which may have systemic effects on the host. Periodontitis initiates systemic inflammation and can be monitored by inflammatory markers like C-reactive protein (CRP) or fibrinogen levels.³ Retention and survival of microorganisms on toothbrushes represent a possible cause of contamination of the mouth. Toothbrushes used regularly become contaminated with microorganisms, which colonize the oral cavity.⁴ Indeed, Gerba's studies show that water droplets in an invisible cloud travel 6 to 8 feet out and up, so the areas of bathroom not directly adjunct to the toilet are still contaminated and contaminated toothbrushes may play a role in both systemic and localized diseases.⁵ Depending on the storage conditions, the toothbrush can, therefore, serve as a reservoir for the reintroduction of potential pathogens.⁴ Thus, it is apparent that present toothbrushes that were basically designed years back need to be re-evaluated.⁶ The new FDA-approved innovative devices like Dental Air Force home dental cleaning system will emerge as a true alternative for conventional tooth brushing in regular practice.⁷ So, this study was outlined to determine the clinical [gingival index (GI), plaque index (PI) and clinical attachment loss (CAL)], laboratory (CRP and glycated hemoglobin) and microbiological (*Aggregatibacter actinomycetemcomitans*, *Fusobacterium nucleatum*, *Porphyromonas gingivalis* and *Prevotella intermedia*) evaluation on efficacy of Dental Air Force home dental cleaning system on type 2 diabetic and nondiabetic adult chronic periodontitis patients.

MATERIALS AND METHODS

The present study was conducted in the Department of Periodontology, Pravara Institute of Medical Sciences, Loni, Maharashtra, India. The research protocol was approved by the University Research and Ethical Committee. Verbal and written informed consent was obtained from all subjects prior to their voluntarily enrollment in the study.

Study Population

The subjects enrolled in this study were selected from the outpatient Department of Periodontology, Rural Dental College and Hospital, Loni, Ahmednagar, Maharashtra, India. The study included a total of 100 subjects of which 50 subjects were type 2 diabetes mellitus patients with chronic periodontitis and 50 subjects were nondiabetic with chronic periodontitis. All the 100 subjects were grouped in four categories and each group was comprised of 25 subjects each as illustrated in Table 1. Exclusion criteria for the patient enrolled in the study were: (1) Presence of any systemic neurological disorder (e.g. epilepsy or schizophrenia), (2) presence of a disease with possible effects on the immune system (e.g. chronic infections or cancer), (3) patient who have received antibiotics or NSAIDS (like ibuprofen) in past 9 to 11 weeks, (4) patients who have received periodontal treatment in past 6 months, (5) pregnant and lactating mother, (6) patient with artificial prosthesis, (7) patients who smokes or consumes tobacco in any form, (8) patients suffering with arthritis, (9) patient with any type of heart disease (MI, CHD, etc), (10) female patient using intrauterine birth control devices or birth control pills, (11) obese individuals (30 and above range as per WHO BMI cutoff for weight categories for Asians) and (12) participants not willing to participate in the study.

Clinical Protocol

After the enrollment of the subjects in the study, phase 1 therapy (scaling and root planing) was done by similar EMS ultrasonic scaler by the same operator to all the 100 subjects

at first visit/baseline only. After phase 1 therapy, subjects under groups B and D were advised to brush twice daily for 5 minutes by modified bass method (technique demonstrated to each subject) and similar medium bristle toothbrush and toothpaste is provided to each of the subject during the study course. After phase 1 therapy, subjects under groups A and C were advised to use Dental Air Force home dental cleaning system (technique demonstrated to each subject) twice daily for 5 minutes. Recall visits were scheduled for all the subjects belonging to all the groups (A to D) on 3rd and 6th month and no phase 1 therapy (scaling and root planing) was done at the recall visits. All the clinical, laboratory and microbiological parameters of 100 subjects enrolled in the clinical trial were recorded at the baseline, 3rd and 6th month.

Clinical Parameters Evaluated

Clinical parameters of periodontal disease that were evaluated were GI, PI and CAL. All the measurements were done by a single operator with William's periodontal probe at base level, 3rd and 6th month for all the groups (A to D).

Laboratory Parameters Evaluated

C-reactive Protein Test

RHELAX-CRP slide test kit was used for the *in vitro* detection of CRP in human serum by qualitative and quantitative rapid latex slide test. RHELAX-CRP slide test for detection of CRP is based on the principle of agglutination. The test specimen (serum) is mixed with RHELAX-CRP latex reagent and allowed to react. If CRP concentration is greater than 0.6 mg/dl a visible agglutination is observed. If CRP concentration is less than 0.6 mg/dl, then no agglutination is observed. No special preparation of the patient was required prior to specimen collection. 2 ml venous blood was collected into sterile disposable tube and processed with centrifuge at 10,000 rpm for serum separation. Only serum was used for testing. If there was delay in testing occurs then samples were stored at 2 to 8°C. All the measurements were done at base level, 3rd and 6th month for all the groups (A to D).

Table 1: Distribution of chronic periodontitis patients in study groups

Groups	Patient clinical protocol	No. of subjects
Group A	Type 2 diabetes mellitus patients with chronic periodontitis receiving phase I therapy followed by use of Dental Air Force home dental cleaning system as regime for oral hygiene	25
Group B	Type 2 diabetes mellitus patients with chronic periodontitis receiving phase I therapy followed by conventional use of toothbrush and toothpaste as regime for oral hygiene	25
Group C	Nondiabetic subjects with chronic periodontitis receiving phase I therapy followed by use of Dental Air Force home dental cleaning system as regime for oral hygiene	25
Group D	Nondiabetic subjects with chronic periodontitis receiving phase I therapy followed by conventional use of toothbrush and toothpaste as regime for oral hygiene	25

Glycated Hemoglobin Estimation (HbA1c)

The venous blood was subjected for assessment of HbA1c test using NycoCard Kit analysis. The NycoCard HbA1c test is a 3-minute point of care test for measurement of HbA1c. NycoCard HbA1c provides an accurate and reliable method to monitor metabolic control for diabetes mellitus. NycoCard[®] HbA1c is a boronate affinity assay. The kit contains test devices with a porous membrane filter, test tubes prefilled with reagent and a washing solution. The reagent contains agents that lyse erythrocytes and precipitate hemoglobin specifically, as well as blue boronic acid conjugate that binds cis-diols of glycated hemoglobin. The NycoCard Reader II is a small color reflectometer which can measure four different analytes by use of specific test cards, one of which is for HbA1c. All the measurements were done at base level, 3rd and 6th month for the type 2 diabetic groups (A and B).

Microbiological Parameters Evaluated

Subgingival plaque samples were collected for specific bacterial examination, i.e. *Aggregatibacter actinomycetemcomitans*, *Fusobacterium nucleatum*, *Porphyromonas gingivalis* and *Prevotella intermedia*. The sample sites were first wiped clean by cotton rolls to remove supragingival plaque and debris. The sample sites were then isolated using the cotton rolls and air dried. Subgingival plaque samples were then collected from the sample sites using the standardized paper point (Dentsply[®]) which were inserted to the depth of the periodontal pocket until resistance was felt. The paper points were retained for 20 seconds in the collection sites. The samples site selected was maxillary first molar in all the cases to maintain the standard protocol. After 20 seconds the paper point was removed from the sample site and immediately transferred into the Robertson's cooked meat medium (RCM) in a test tube for specific bacterial culturing. The media was transported to the microbiological laboratory. In the laboratory the RCM was subjected to vortex homogenization for 60 seconds before incubated anaerobically (Gas pack system) for 2 to 3 days. After 2 to 3 days incubation the growth in the RCM was subcultured on to Trypticase soy agar and Brucella agar. The bacterial growth in Trypticase soya agar and Brucella agar was assessed by semiquantitative method. All the measurements were done at base level, 3rd and 6th month for all the groups (A to D). Standard loop of 4 mm diameter which can hold 0.01 mm of RCM was used and spread on to the culture plates, colony forming units (CFU) were counted using colony counter.

Dental Air Force Home Dental Cleaning System

Dental Air Force is a home dental cleaning device. It is an electrical delivery device that uses a 1/8th HP oil-less electric air compressor air source with twin pistons connected to a handpiece by a pneumatic cord directed through a handpiece and tip where air at 40 psi through a 0.020 size orifice has the introduction of a slurry of dental cleaner. This produces a jet stream of wet abrasive whereby the user directs the cleaner components and air into the sites between the teeth and below the gum line. Dental Air Force through electron microscopy has been shown to be much less abrasive than a toothbrush and toothpaste combination. There is no electricity in the handpiece and the air source can be turned on and off remotely through a pneumatic button on the handpiece. The manufacturer recommends twice a day usage for 5 minutes as a part of the regular oral hygiene. Dental Air Force home dental cleaning system used in this study is approved by FDA Vide No K001493 as safety device for plaque removal in order to prevent gingivitis. The appliance uses a precision jet of air to deliver water and dental cleaner to 'power wash' the mouth. Dental Air Force uniquely dispenses the dental cleaner by you controlling the amount of cleaner that is dispensed in your mouth. One normal application uses one teaspoon of dental cleaner. The cleaner ingredients include sodium bicarbonate, the most widely accepted and totally natural buffering agent that promotes a neutral environment. It also contains mint flavoring, Xylitol and Stevia as natural sweeteners. The formula is free of sodium lauryl sulfate, the ingredient in most toothpaste that causes sensitivity and irritation.⁸

RESULTS

Distribution of mean and standard deviation values of all the clinical, laboratory and microbiological parameters of all the groups (A to D) were illustrated in Tables 2 and 3. After applying Student's paired t-test there was a highly significant decrease in clinical, laboratory and microbiological parameters from baseline to 6 months in groups A, B, C and D (i.e. $p < 0.01$). It was observed that group C showed more significant decrease as compared to group A (i.e. $p < 0.01$). Also by applying Student's unpaired t-test there was a highly significant difference between mean values of all clinical, laboratory and microbiological parameters in group A vs B, group A vs C, group A vs D, group B vs C, group B vs D, and group C vs D (i.e. $p < 0.01$). It was concluded that the mean clinical, laboratory and microbiological parameters in group C showed larger decrease than group A ($p < 0.01$) as shown in Graph 1 (A vs B), Graph 2 (C vs D) and Graph 3 (A vs C). By applying two-way ANOVA (Tukey-Kramer multiple

Table 2: Distribution of mean and standard deviation values (mean \pm SD) of all clinical and laboratory parameters at baseline, 3rd and 6th months in all the experimental groups

Groups	Observation	GI	PI	CAL	CRP	HbA1c
Group A	Baseline	2.62 \pm 0.25	2.56 \pm 0.24	5.91 \pm 0.32	2.5 \pm 0.59	8.62 \pm 1.08
	3rd month	1.0 \pm 1.88	1.51 \pm 0.12	3.71 \pm 0.74	1.42 \pm 0.73	7.96 \pm 1.12
	6th month	0.70 \pm 0.21	1.0 \pm 0.28	2.40 \pm 0.61	0.94 \pm 0.75	7.58 \pm 1.17
Group B	Baseline	2.95 \pm 0.23	2.65 \pm 0.26	5.69 \pm 0.92	3.12 \pm 0.48	8.40 \pm 0.79
	3rd month	1.18 \pm 0.19	1.34 \pm 0.20	4.23 \pm 0.72	2.28 \pm 0.77	8.10 \pm 0.81
	6th month	1.21 \pm 0.23	1.27 \pm 0.27	3.38 \pm 0.49	2.16 \pm 1.01	7.93 \pm 0.81
Group C	Baseline	2.53 \pm 0.31	2.48 \pm 0.24	5.88 \pm 3.69	2.78 \pm 0.57	5.56 \pm 0.51
	3rd month	1.55 \pm 0.25	1.1 \pm 0.11	3.69 \pm 0.55	1.70 \pm 0.70	5.34 \pm 0.51
	6th month	0.82 \pm 0.37	0.97 \pm 0.06	2.52 \pm 0.50	1.22 \pm 0.74	5.26 \pm 0.52
Group D	Baseline	2.64 \pm 0.28	2.6 \pm 0.26	5.8 \pm 0.25	2.95 \pm 0.42	5.48 \pm 0.52
	3rd month	1.41 \pm 0.16	1.19 \pm 0.21	4.09 \pm 0.51	2.11 \pm 0.52	5.36 \pm 0.52
	6th month	1.42 \pm 0.14	1.21 \pm 0.19	3.29 \pm 0.43	1.99 \pm 0.87	5.32 \pm 0.51

GI: Gingival index; PI: Plaque index; CAL: Clinical attachment loss; CRP: C-reactive protein; HbA1c: Glycated hemoglobin

Table 3: Distribution of mean and standard deviation values (mean \pm SD) of all microbiological parameters at baseline, 3rd and 6th months in all the experimental groups

Groups	Observation	Aa	Fn	Pg	Pi
Group A	Baseline	26.72 \pm 4.47	31.16 \pm 5.71	26.36 \pm 5.31	24.8 \pm 6.34
	3rd month	13.48 \pm 3.55	16.96 \pm 2.26	13.04 \pm 3.51	12.52 \pm 3.74
	6th month	4.64 \pm 1.7	5.0 \pm 1.76	4.40 \pm 2.12	5.24 \pm 2.63
Group B	Baseline	31.12 \pm 7.5	32.32 \pm 5.81	30.4 \pm 6.09	31.72 \pm 6.19
	3rd month	26.84 \pm 7.23	29.52 \pm 5.91	27.04 \pm 5.26	28.52 \pm 5.93
	6th month	24.08 \pm 7.32	27.04 \pm 5.83	24.72 \pm 4.95	25.96 \pm 5.79
Group C	Baseline	28.24 \pm 3.5	29.72 \pm 3.71	28.04 \pm 3.07	28.4 \pm 3.45
	3rd month	17.32 \pm 4.19	18.24 \pm 5.25	13.68 \pm 3.69	16.4 \pm 5.47
	6th month	7.32 \pm 4.25	6.08 \pm 1.61	5.76 \pm 2.0	6.48 \pm 2.81
Group D	Baseline	25.88 \pm 4.62	28.4 \pm 6.49	26.92 \pm 5.14	28.76 \pm 4.64
	3rd month	23.36 \pm 4.37	26.32 \pm 6.42	24.28 \pm 4.73	26.04 \pm 4.38
	6th month	20.96 \pm 4.31	24.44 \pm 6.32	21.2 \pm 3.38	23.04 \pm 4.35

Aa: *Aggregatibacter actinomycetemcomitans*, Fn: *Fusobacterium nucleatum*, Pg: *Porphyromonas gingivalis*, Pi: *Prevotella intermedia*

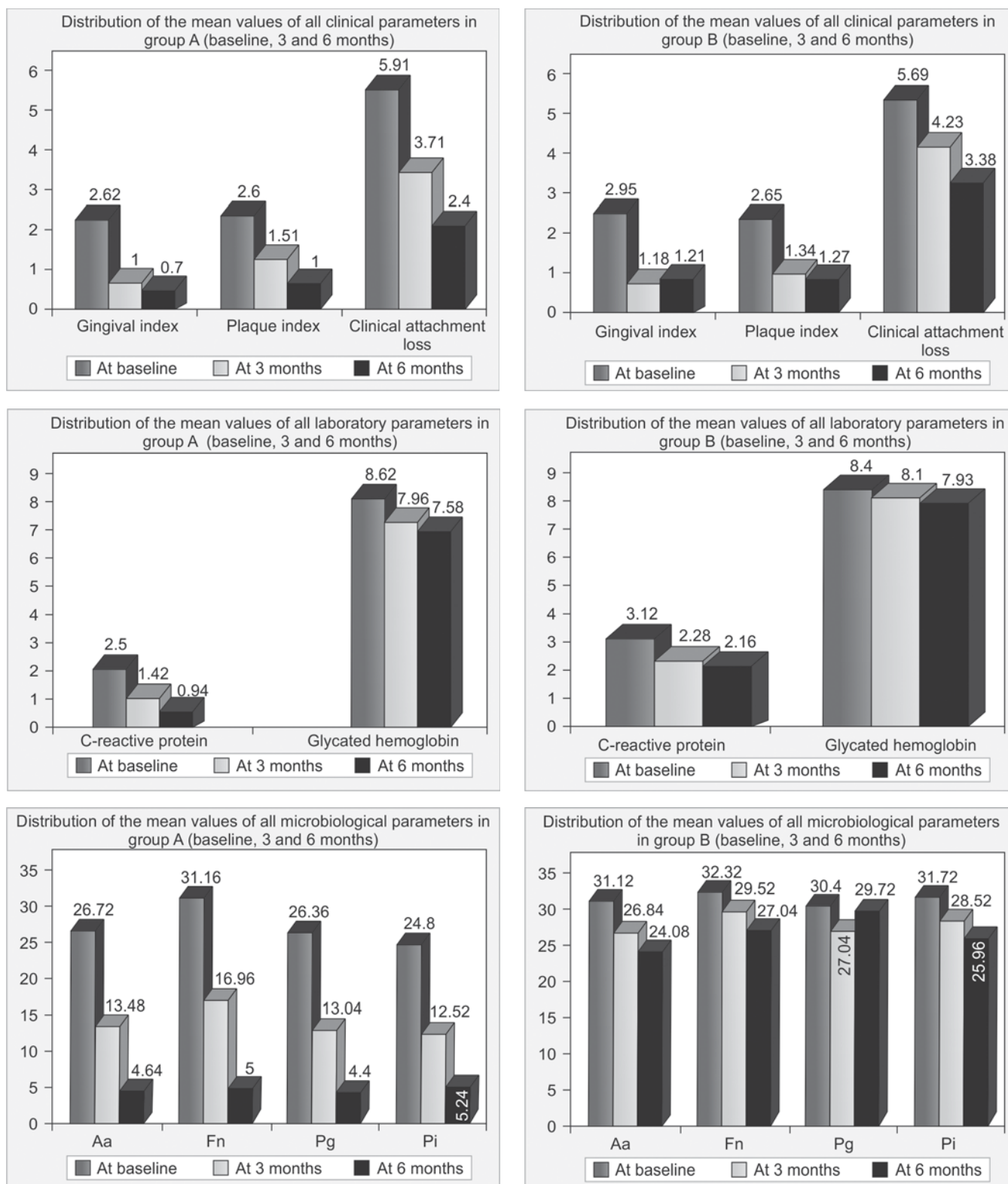
comparison test) test there is a significant difference between groups A, B, C and D when compared together in respect to clinical, laboratory and microbiological parameters ($p < 0.05$).

DISCUSSION

The oral cavity is a portal of entry as well as the site of disease for microbial infections that affect general health. Periodontitis has been proposed as having an etiological or modulating role in cardiovascular disease, diabetes, respiratory disease and adverse pregnancy outcome and several mechanisms have been proposed to explain or support such theories and oral lesions are indicators of disease progression and oral cavity can be a window to overall health and body systems.⁹ Locally produced inflammatory mediators such as CRP, interleukins-1 beta (IL-1 β), interleukins 6 (IL-6), tumor necrosis factor alpha (TNF- α) are the key modulating agents in cardiovascular disease. Periodontitis creates a burden low level of systemic inflammatory reactants (CRP) bacterial pathogens, antigens, endotoxins and inflammatory cytokines (IL-1, IL-6, TNF- α)

that contribute to the process of atherogenesis and thromboembolic events.¹⁰ The key for optimal oral health that lead to better systemic health is achieved by regular daily oral hygiene, Dental Air Force home dental cleaning system showed significant results in achieving the same as compared to conventional toothbrush.

The subjects (groups A and C) using Dental Air Force home dental cleaning system showed more significant clinical, laboratory and microbiological results in both type 2 diabetic and nondiabetic adult chronic periodontitis patients as compared to subjects (groups B and D) using toothbrush and toothpaste after phase 1 therapy (scaling and root planing). The possible mechanism of greater efficiency as compared to toothbrush is that Dental Air Force home dental cleaning system uses air and a dental cleaner with water to break through the plaque barrier. The air oxygenates the spaces between teeth and along the gum line, making it difficult for the anaerobic plaque-causing bacteria to live. Sodium bicarbonate is a neutralizing agent that acts on the acids produced by the bacteria. It is an abrasive that breaks up

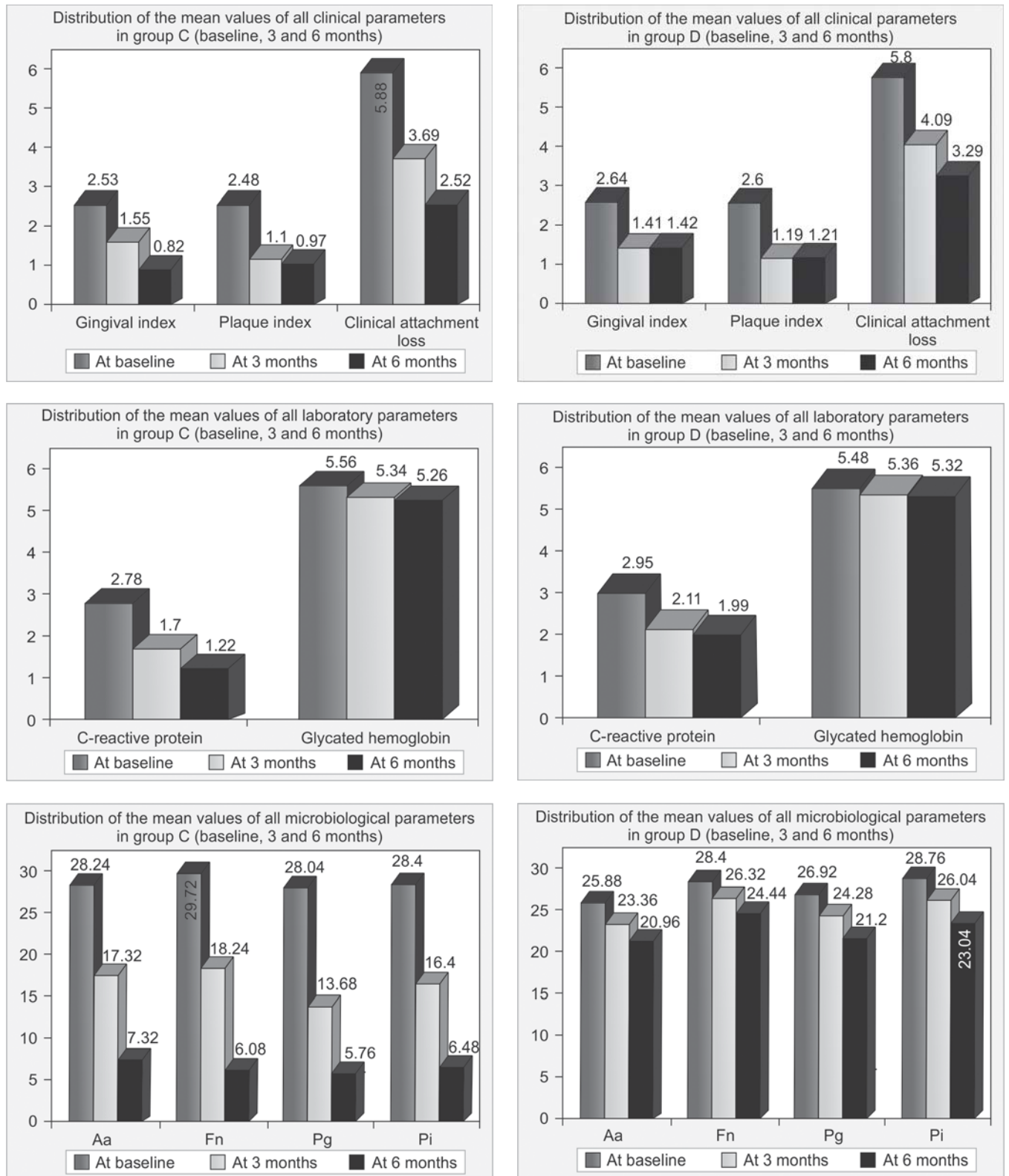


Graph 1: Comparison of groups A vs B

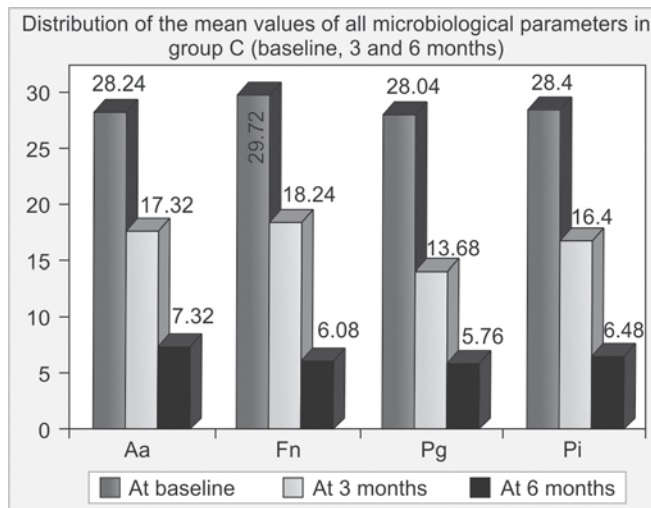
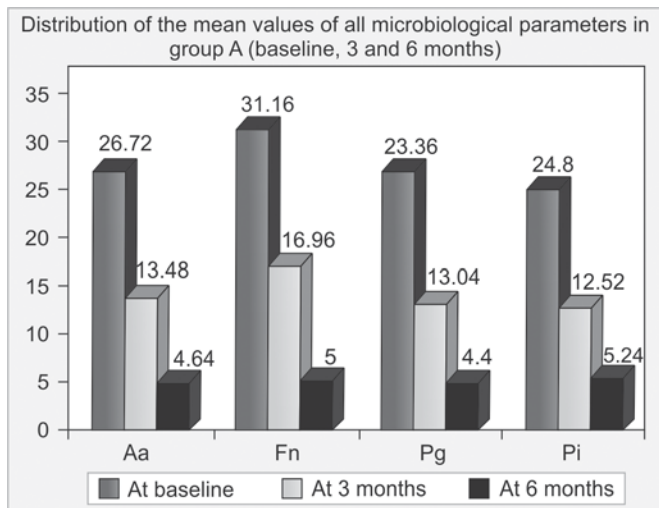
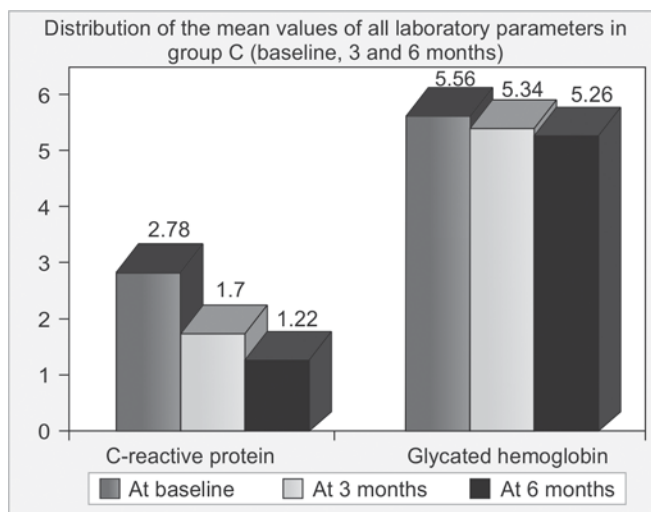
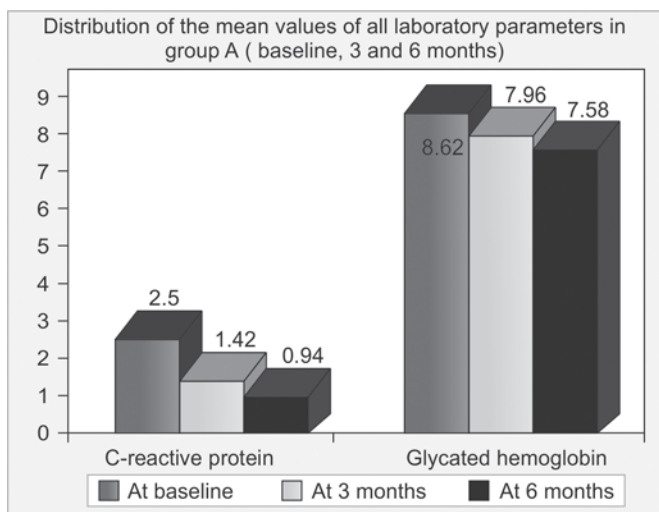
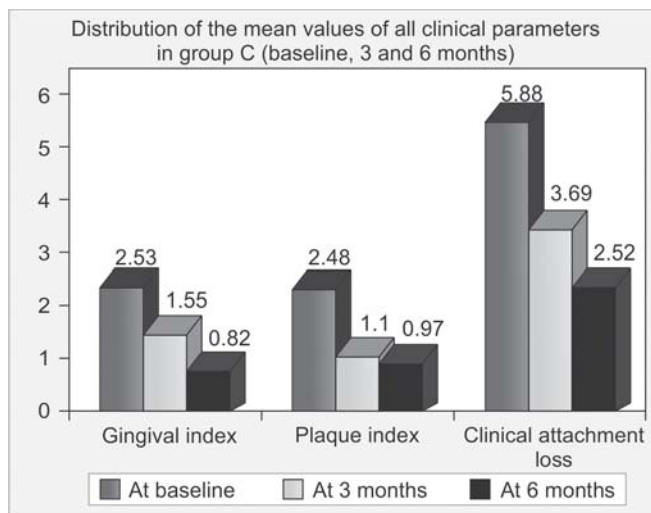
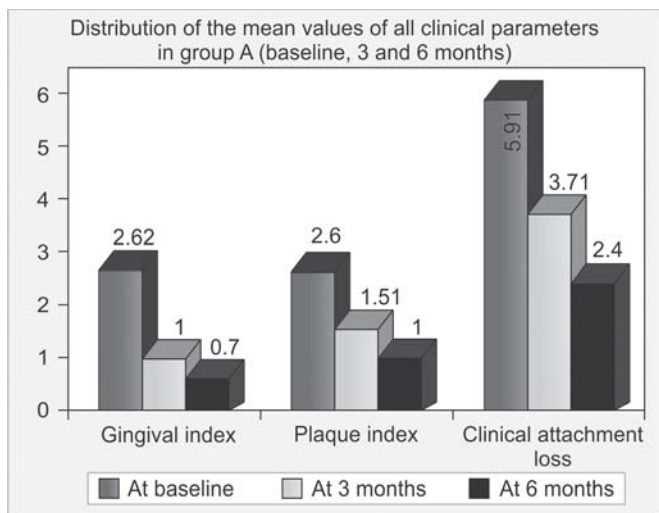
the plaque's sticky film. It also removes the odor caused by the plaque. The water flushes away the bacteria and debris off the surfaces of the teeth.⁸ Dental Air Force home dental cleaning system with access to subgingival area lead to removal of biofilm and prevent further proliferation of periodontopathic microorganisms.

CONCLUSION

The results of this study showed that there was positive correlation with periodontitis and systemic health observed by elevated levels of CRP and HbA1c levels. Further this study it was established that with regular use of Dental Air Force home dental cleaning system as oral hygiene regime there was



Graph 2: Comparison of groups C vs D



Graph 3: Comparison of groups A vs C

significant reduction in all the clinical, laboratory and microbiological parameters of all the adult chronic periodontitis subjects as compared to toothbrush.

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